

## United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/673,686	07/25/2001	GALINA MIKHAILIVNA ERKHOVA	ERKHOV-1 PCT	2044
2292	7590 05/05/2006		EXAM	INER
	WART KOLASCH &	CANELLA, KAREN A		
PO BOX 747 FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
	,		1643	
			DATE MAILED: 05/05/200	6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)		
09/673,686	ERKHOVA, GALINA MIKHAILIVNA		
Examiner	Art Unit		
Karen A. Canella	1643		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 10 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires <u>3</u> months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The Notice of Appeal was filed on 10 February 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): none. 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7.  $\square$  For purposes of appeal, the proposed amendment(s): a)  $\square$  will not be entered, or b)  $\square$  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: Claim(s) withdrawn from consideration: \_\_\_\_\_. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. 

The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 13. Other: \_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because: it fails to overcome the rejection under 112, first paragraph. Applicant argues that the production of antiserum using desorption to remove undesired antibodies is well known in the art and cites Yoshinaga et al, Allen et al, Ro et al and Dresse et al wherein antiserum specific to a specific tissue or cell type is desopbed by a related tissue or cell type, and concludes that it si well known in the art how to perform absorption procedures to removed unwanted antibodies against background antigens. This has been considered but not found to be persuasive. In the instant case the antiserum is not confined to a reactivity against a specific organ or tissue type. The antiserum would be reactive against a population of fetal antigens, therefore it would not be reasonable to expect that a single organ type of a mature anaimal would suffice for the desorption. Applicant argues that it would not be undue experimentation to try a dozen or more combination of organ types. This has been considered but not found persuasive because the resulting antiserum must be able to provide an experiemtnal result which can diangose the presence of cancer by using the equation of claim 11. Therefore the simple aggregation test suggested by applicant would not suffice. Further, there are more that a few dozen absprption experiments which one of skill in the art would be forced to carry out for the production of the antiserum. Applicant argues that the specification provides a working example,;however it is noted that the specification does not detail the production of the antiserum. applicant argues that post-filing date art demosntrate the clinical usefulness of testing pateints with said antiserum. The examiner does not doubt the usefulness of the specific antiserum of the instant specification in contributing to cancer screening, what is in question is the level of experiemtnation needed for one of skill in the art to make the antiserum of the instant specification..

> MARENA CAMELA PH.D WARENA CAMELA PH.D WARENA CAMELA PH.D WARENA CAMELA PH.D

> > KAREN A. CANELLA PH.D